

WHAT IS CLAIMED IS:

1. A monoclonal antibody, or binding fragment thereof, which binds specifically to an antigen on the surface of small cell lung cancer (SCLC) cells, the antigen being characterized in that
 - (i) it is a single polypeptide having a molecular weight of about 200 kDa as determined by SDS-PAGE under reducing conditions;
 - (ii) it is absent from human multiple myeloma cells; and
 - (iii) it is glycosylated.
2. The monoclonal antibody, or binding fragment thereof, according to claim 1, which is produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) and having ATCC Accession Number selected from the group consisting of ATCC Accession No. PTA-2360 (MoAb 51.2), ATCC Accession No. PTA-2358 (MoAb 37.14) and ATCC Accession No. PTA-2357 (MoAb 109.12).
3. The monoclonal antibody, or binding fragment thereof, according to claim 1, which binds specifically to an antigen on the surface of small cell lung cancer (SCLC) cells, the antigen being further characterized in that (iv) it is absent from neuroendocrine cells.
4. The monoclonal antibody, or binding fragment thereof, according to claim 3, which is produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) and having ATCC Accession Number PTA-2357 (MoAb 109.12).
5. A monoclonal antibody, or binding fragment thereof, which binds specifically to an antigen on the surface of small cell lung cancer (SCLC) cells, the antigen being characterized in that

- (i) it has a molecular weight of about 35 kDa to about 50 kDa as determined by SDS-PAGE under reducing conditions;
- (ii) it is absent from human multiple myeloma cells and neuroendocrine cells; and
- (iii) it is glycosylated.

6. The monoclonal antibody, or binding fragment thereof, according to claim 5, which is produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) and having ATCC Accession Number PTA-2358 (MoAb 37.14).

7. A monoclonal antibody, or binding fragment thereof, which (i) binds specifically to a conformational epitope of an antigen on the surface of small cell lung cancer (SCLC) cells, and (ii) is produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) having ATCC Accession No. PTA-2359 (MoAb 26.1).

8. A monoclonal antibody, or binding fragment thereof, selected from the group consisting of (i) a monoclonal antibody produced from the hybridoma cell line deposited at the American Type Culture Collection (ATCC) having ATCC Accession No. PTA-2358 (MoAb 37.14), a monoclonal antibody produced from the hybridoma cell line deposited at the American Type Culture Collection (ATCC) having ATCC Accession No. PTA-2360 (MoAb 51.2), or a hybridoma cell line deposited at the American Type Culture Collection (ATCC) having ATCC Accession No. PTA-2357 (MoAb 109.12), which antibodies bind to a cell surface glycoprotein antigen on human small cell lung cancer cells, and (ii) antibodies that are capable of binding to the same antigenic determinant as do the monoclonal antibodies produced by the hybridoma cell lines deposited at the American Type Culture Collection (ATCC) having ATCC Accession No. PTA-2358 (MoAb 37.14), having ATCC Accession No.

PTA-2360 (MoAb 51.2), or having ATCC Accession No. PTA-2357 (MoAb 109.12).

9. A monoclonal antibody, or binding fragment thereof, selected from the group consisting of a monoclonal antibody produced from the hybridoma cell line deposited at the American Type Culture Collection (ATCC) having ATCC Accession No. PTA-2360 (MoAb 51.2), a hybridoma cell line deposited at the American Type Culture Collection (ATCC) having ATCC Accession No. PTA-2357 (MoAb 109.12), a hybridoma cell line deposited at the American Type Culture Collection (ATCC) having ATCC Accession No. PTA-2358 (MoAb 37.14) and a hybridoma cell line deposited at the American Type Culture Collection (ATCC) having ATCC Accession No. PTA--2359 (MoAb 26.1).

10. The monoclonal antibody, or binding fragment thereof, according to claim 8, wherein the cell surface glycoprotein antigen is present on human small cell lung cancer cells and is absent from human multiple myeloma cells.

11. The monoclonal antibody, or binding fragment thereof, according to claim 8, wherein the cell surface glycoprotein antigen recognized by the monoclonal antibody or binding fragment thereof is present on the surface of human small cell lung cancer cells and is a single glycosylated polypeptide having a molecular weight of about 200 kDa as determined by SDS-PAGE under reducing conditions.

12. The monoclonal antibody or binding fragment thereof, according to any one of claims 1, 5, or 9, wherein the binding fragment is selected from the group consisting of Fab fragments, F(ab)₂ fragments, Fab' fragments, F(ab')₂ fragments, Fd fragments, Fd' fragments and Fv fragments.

13. An anti-idiotypic antibody which mirrors the binding site of the antibody according to claim 9.

14. A hybridoma cell line which produces a monoclonal antibody which

binds specifically to an antigen on the surface of small cell lung cancer (SCLC) cells, the antigen being characterized in that

- (i) it is a single polypeptide having a molecular weight of about 200 kDa as determined by SDS-PAGE under reducing conditions;
- (ii) it is absent from human multiple myeloma cells; and
- (iii) it is glycosylated.

15. The hybridoma cell line according to claim 14, which is deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-2360 (MoAb 51.2).

16. The hybridoma cell line according to claim 14, which is deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-2357 (MoAb 109.12).

17. The hybridoma cell line according to claim 14, which is deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-2358 (MoAb 37.14).

18. The hybridoma cell line according to claim 14, wherein the antigen on the surface of small cell lung cancer (SCLC) cells which is bound by the produced monoclonal antibody, or binding fragment thereof, is further characterized in that (iv) it is absent from neuroendocrine cells.

19. The hybridoma cell line according to claim 18, which is deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-2357 (MoAb 109.12).

20. A hybridoma cell line which produces a monoclonal antibody which binds specifically to an antigen on the surface of small cell lung cancer (SCLC) cells,

the antigen being characterized in that

- (i) it has a molecular weight of about 35 kDa to about 50 kDa as determined by SDS-PAGE under reducing conditions;
- (ii) it is absent from human multiple myeloma cells and neuroendocrine cells; and
- (iii) it is glycosylated.

21. The hybridoma cell line according to claim 20, which is deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-2358 (MoAb 37.14).

22. An antibody-recognized surface antigen present on human small cell lung cancer cells and having the characteristics of (i) being a single polypeptide having a molecular weight of about 200 kDa as determined by SDS-PAGE under reducing conditions; (ii) being absent from human multiple myeloma cells; (iii) being absent from or underexpressed on neuroendocrine cells; and (iv) being glycosylated.

23. An antibody-recognized surface antigen present on human small cell lung cancer cells, the antigen having the characteristics of (i) having a molecular weight of about 35 kDa to about 50 kDa as determined by SDS-PAGE under reducing conditions; (ii) being absent from human multiple myeloma cells and human neuroendocrine cells; and (iii) being glycosylated.

24. The antibody-recognized surface antigen according to claim 22, wherein the antibody that binds to the antigen is a monoclonal antibody produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) and selected from the group consisting of the hybridoma cell line having ATCC Accession No. PTA-2358 (MoAb 37.14), the hybridoma cell line having ATCC Accession No. PTA-2360 (MoAb 51.2) and the hybridoma cell line having ATCC Accession No. PTA-2357 (MoAb 109.12).

25. The antibody-recognized surface antigen according to claim 23, wherein the antibody that binds to the antigen is a monoclonal antibody produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) and having ATCC Accession No. PTA-2358 (MoAb 37.14).

26. A method of inhibiting or killing small cell lung cancer (SCLC) cells, comprising: providing to a patient in need thereof the monoclonal antibody, or binding fragment thereof, according to any one of claims 1, 5, or 9, under conditions and in an amount sufficient for the binding of the monoclonal antibody, or binding fragment thereof, to the SCLC cells, thereby causing inhibition or killing of the SCLC cells by the immune cells of the patient.

27. The method according to claim 26, further wherein the monoclonal antibody is conjugated with a cytotoxic moiety.

28. The method according to claim 27, wherein the cytotoxic moiety is a chemotherapeutic agent, a photoactivated toxin, or a radioactive agent.

29. The monoclonal antibody, or binding fragment thereof, according to claim 1, claim 5, or claim 9 bound to a solid matrix.

30. A method of localizing small cell lung cancer (SCLC) cells in a patient, comprising:

- (a) administering to the patient a detectably-labeled monoclonal antibody, or binding fragment thereof, according to any one of claims 1, 5, or 9;
- (b) allowing the detectably-labeled monoclonal antibody, or binding fragment thereof, to bind to the SCLC cells within the patient; and
- (c) determining the location of the labeled monoclonal antibody or binding fragment thereof, within the patient.

31. A method of detecting the presence and extent of small cell lung cancer

in a patient, comprising: determining the level of the antigen according to any of claims 22 to 25 in a sample of bodily fluid from the patient and correlating the quantity of the antigen with the presence and extent of the small cell lung cancer disease in the patient.

32. A method of monitoring the effectiveness of therapy for small cell lung cancer disease, comprising: periodically measuring changes in the level of the antigen according to any of claims 22 to 25 in a body fluid sample taken from a patient undergoing the therapy, and correlating the change in level of the antigen with the effectiveness of the therapy, wherein a lower level of antigen determined at a later time point relative to the level of antigen determined at an earlier time point during the course of therapy indicates effectiveness of the therapy for small cell lung cancer disease.

33. A method of diagnosing the presence of small cell lung cancer in a patient, comprising:

- (a) measuring the levels of the antigen according to any of claims 22 to 25 in cells, tissues, or body fluids of the patient; and
- (b) comparing the measured levels of the antigen of (a) with levels of the antigen in cells, tissues, or body fluids from a normal human control, wherein an increase in the measured levels of the antigen in the patient versus the normal control is associated with the presence of small cell lung cancer.

34. A method of imaging small cell lung cancer in a patient, comprising administering to the patient the antibody according to any one of claims 1, 5, or 9, wherein the antibody is detectably labeled with paramagnetic ions or with a radioisotope.

35. A pharmaceutical composition comprising the monoclonal antibody, or binding fragment thereof, according to any one of claims 1, 5, or 9, and a

pharmaceutically acceptable carrier, excipient, or diluent.

36. The pharmaceutical composition according to claim 35, wherein the monoclonal antibody, or binding fragment thereof, recognizes an antigen present on the surface of human small cell lung cancer cells, but not on normal lung cells, or on human multiple myeloma cells.

37. A pharmaceutical composition comprising a monoclonal antibody, or binding fragment thereof, wherein the antibody

(a) is selected from the group consisting of (i) a monoclonal antibody produced from the hybridoma cell line deposited at the American Type Culture Collection (ATCC) and having ATCC Accession No. PTA-2360 (MoAb 51.2), (ii) a monoclonal antibody produced from the hybridoma cell line deposited at the American Type Culture Collection (ATCC) and having ATCC Accession No. PTA-2357 (MoAb 109.12); (iii) a monoclonal antibody produced from the hybridoma cell line deposited at the American Type Culture Collection (ATCC) and having ATCC Accession No. PTA-2358 (MoAb 37.14), (iv) a monoclonal antibody produced from the hybridoma cell line deposited at the American Type Culture Collection (ATCC) and having ATCC Accession No. PTA-2359 (MoAb 26.1); wherein the monoclonal antibodies (i)-(iv) bind to a cell surface antigen on human small cell lung cancer cells;

(b) is an antibody that is capable of binding to the same antigenic determinant as does the monoclonal antibody, or a binding fragment thereof, produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-2360 (MoAb 51.2), or produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-2357 (MoAb 109.12), or produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-2358 (MoAb 37.14), or produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC) under ATCC Accession No. PTA-2359

(MoAb 26.1); and a pharmaceutically acceptable carrier, excipient, or diluent.

38. The monoclonal antibody according to any one of claims 1, 5, or 9, labeled with a detectable moiety.

39. The monoclonal antibody according to claim 38, wherein the detectable moiety is selected from the group consisting of a fluorophore, a chromophore, a radionuclide, a chemiluminescent agent, a bioluminescent agent and an enzyme.

40. A method of inhibiting or killing pancreatic cancer cells, comprising: providing to a patient in need thereof the monoclonal antibody, or binding fragment thereof, according to any one of claims 1, 5, or 9, under conditions and in an amount sufficient for the binding of the monoclonal antibody, or binding fragment thereof, to the SCLC cells, thereby causing inhibition or killing of the SCLC cells by the immune cells of the patient.

41. The method according to claim 40, further wherein the monoclonal antibody is conjugated with a cytotoxic moiety.

42. The method according to claim 41, wherein the cytotoxic moiety is a chemotherapeutic agent, a photoactivated toxin, or a radioactive agent.

43. A method of localizing pancreatic cancer cells in a patient, comprising:

- (a) administering to the patient a detectably-labeled monoclonal antibody, or binding fragment thereof, according to any one of claims 1, 5, or 9;
- (b) allowing the detectably-labeled monoclonal antibody, or binding fragment thereof, to bind to the pancreatic cancer cells within the patient; and
- (c) determining the location of the labeled monoclonal antibody or binding fragment thereof, within the patient.

44. The method according to claim 43, wherein the detectable label is

selected from the group consisting of a fluorophore, a chromophore, a radionuclide, a chemiluminescent agent, a bioluminescent agent and an enzyme.

45. A method of imaging pancreatic cancer in a patient, comprising administering to the patient the antibody according to any one of claims 1, 5, or 9, wherein the antibody is detectably labeled with paramagnetic ions or with a radioisotope.

46. A method of diagnosing or detecting pancreatic tumor cells or cancer cells in a patient, comprising: incubating the monoclonal antibody, or binding fragment thereof, according to any one of claims 1, 5, or 9 with pancreatic cells from a patient; and detecting the binding of the monoclonal antibody to the pancreatic cells, thereby diagnosing or detecting pancreatic tumor cells or cancer cells in the patient.

47. The method according to claim 46, wherein the monoclonal antibody is MoAb 109.12 having ATCC Accession No. PTA-2357.

48. The method according to claim 46, wherein the monoclonal antibody is labeled with a detectable label selected from the group consisting of a fluorophore, a chromophore, a radionuclide, a chemiluminescent agent, a bioluminescent agent and an enzyme.

49. A pharmaceutical composition comprising the monoclonal antibody, or binding fragment thereof, according to any one of claims 1, 5, or 9, and a pharmaceutically acceptable carrier, excipient, or diluent, wherein the monoclonal antibody, or binding fragment thereof, recognizes an antigen present on the surface of human pancreatic cancer cells.